

## **REMARKS**

This Amendment is being filed along with a Request for Continued Examination (RCE) to place the application in condition for allowance. Applicants appreciate the courtesies extended by Examiner Menon in granting an interview with the undersigned on May 6, 2005. The substance of the interview is discussed below.

In the Final Office Action mailed on December 2, 2004, the Examiner rejected claims 1-20 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,177,013 to Thomas et al. ("the '013 patent") in view of U.S. Patent No. 5,840,190 to Scholander et al. (Scholander). Applicants respectfully traverse these rejections.

Claims 1-20 are pending in this application. By this Amendment, claim 1 is cancelled without prejudice, claims 2-20 are amended, and claims 21-25 are added to more appropriately claim the present invention. Prompt consideration of this Amendment and allowance of the application are earnestly requested.

At the outset, Applicants respectfully submit that the "Attachment to Interview Summary" prepared on May 6, 2005, does not accurately reflect Applicants' position regarding motivation to combine. In particular, the Summary states that: "Applicants extended further arguments as follows." "motivation to combine: there is a motivation to combine the references in col. 1, lines 15-33." Applicants note that a lack of motivation to combine was strenuously argued during the interview, and at no time did Applicants' representative agree that there is any motivation to combine the applied references in the manner proposed by the Examiner. Should the Examiner disagree with Applicants' position regarding this mischaracterization, Applicants ask that the Examiner respond to this issue in his reply to this Amendment.

As noted during the interview, there would not have been any motivation to combine the teachings of Scholander and Thomas at the time of the invention. The Thomas references (both the '013 and '475 patents) are directed to an apparatus for avoiding the activation of the contact phase of blood, while Scholander is directed to improving the biocompatibility of a membrane surface to avoid coagulation. Activation of the contact phase is very different from coagulation.

Turning to the Examiner's rejections, Applicants respectfully traverse the 103(a) rejections based on the '013 patent because the '013 patent is not prior art to this application under the "common assignee" exception provided by 35 U.S.C. §§ 102(e) and 103(c). If the '013 patent was being used as a § 102 reference, it would fall under § 102(e)(1), which states that "the invention was described in an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent." Section 103(c), further states, however, that "[s]ubject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same persons or subject to an obligation of assignment to the same person." The assignee in the '013 patent is Hospal Industrie, while the inventors in the present case were under an obligation to assign this application to Hospal Industrie at the time of the invention. Therefore, the '013 patent is not prior art to the present application.

The above issue was discussed during the interview of May 6, 2005, and the Examiner raised U.S. Patent No. 6,010,475 to Thomas et al. ("the '475 patent") as a

potential alternative prior art reference. Applicants have taken the '475 patent into consideration in preparing this Amendment.

New claim 21 recites, among other things, a composite semipermeable membrane having a semipermeable support base layer with pores. On the surface of the base layer lies “a first coated layer having a cationic polymer...comprising chains having an associated steric hindrance that prevents said chains from penetrating into said pores of the support base layer.” New claim 21 further recites a composite semipermeable membrane having “a second coated layer provided on the first coated layer, said second coated layer having an anticoagulant agent carrying anionic groups.”

New claim 25 recites, among other things, a method for preparing a composite semipermeable membrane comprising consecutive steps. The first step involves “coating a semipermeable support base layer having pores with a first layer having a cationic polymer...said cationic polymer further comprising chains having an associated steric hindrance that prevents said chains from penetrating into said pores of the support base layer.” The second step recited in the method of new claim 25 involves “coating the first layer with a second layer, said second layer having an anticoagulant agent having anionic groups.”

Applicants respectfully traverse the Examiner’s rejection of pending claims 1-20, under 35 U.S.C. § 103(a) as being unpatentable over Thomas (“the '013 patent”) in view of Scholander. To the extent the Examiner’s rejections under 35 U.S.C. § 103(a) are understood, Applicants note that in order to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of

ordinary skill in the art, to modify the reference or to combine teachings of the references. Second, there must be a reasonable expectation of success. Finally, the prior art references, when combined, must teach or suggest all the claim limitations. See M.P.E.P. § 2143. Applicants respectfully submit that the Examiner failed to establish a *prima facie* case of obviousness, however, the Examiner's rejections are moot in light of Applicants' cancellation of claim 1, addition of claims 21-25, and amendment of claims 2-20.

Insofar as the Examiner's rejections under 35 U.S.C. § 103(a) are relevant to amended claims 2-20 and new claims 21-25, Applicants respectfully submit that new claim 21, for example, is neither anticipated by, nor obvious over the '013 patent in view of Scholander (or the '475 patent in view of Scholander) at least because none of those references raised by the Examiner, teach or suggest the claimed composite semipermeable membrane comprising "a semipermeable support base layer having pores...a first coated layer having a cationic polymer...comprising chains with sufficiently large steric hindrance precluding said chains from penetrating into said pores of the support base layer; and a second coated layer atop the first coated layer, said second coated layer having an anticoagulant agent carrying anionic groups." (Emphasis added).

During the interview of May 6, 2005, the Examiner asserted that in Scholander, cationic polymer is still in the surface of the membrane despite the reference's teaching that the cationic polymer is incorporated into the membrane during the membrane's formation. Nonetheless, Scholander fails to teach "a first coated layer [atop the support base layer] having a cationic polymer...comprising chains having an associated steric

hindrance that prevents said chains from penetrating into said pores of the support base layer.” Neither the '013 patent nor the '475 patent teach or suggest this limitation either.

Applicants further submit that new claim 25, for example, is neither anticipated by, nor obvious over Scholander, the '013 patent, or the '475 patent, or any combination of those references, at least because none of those references teach or suggest a method for preparing a composite semipermeable membrane comprising the “consecutive steps of: coating a semipermeable support base layer having pores with a first layer having a cationic polymer...said cationic polymer further comprising chains having an associated steric hindrance that prevents said chains from penetrating into said pores of the support base layer; and coating the semipermeable support base layer containing the first layer with a second layer, said second layer having an anticoagulant agent having anionic groups” (emphasis added).

Moreover, in addition to reasons discussed during the interview, there is no motivation to combine Scholander and Thomas (the '013 or '475 patents) in the manner proposed by the Examiner because one of ordinary skill would not directly combine heparin with a cationic surfactant. In particular, Applicants respectfully direct the Examiner's attention to an article entitled “Heparin,” included in an IDS filed with this Amendment and accompanying the RCE. This article provides additional evidence that one of skill in the art at the time of this invention would not have even attempted to combine the teachings of Scholander and Thomas. According to this article, it was known to introduce a cationic polymer to a biological surface before treatment with heparin. It was further known, however, that heparin and cationic surfactants are slowly released from the surface when contacted by blood, which can be problematic because

it is unstable. The membrane consistent with the present invention solves this problem by providing a first coated layer having a cationic polymer and a second coated layer having an anticoagulant agent carrying anionic groups. Applicants advise that such membranes have greater stability.

New claims 21 and 25, therefore, are allowable over the Examiner's proposed combination of Scholander and the '013 patent, or Scholander and the '475 patent.

While of different scope, amended claims 12 and 15, reciting an exchanger and a method for reducing the thrombogenic character of an exchanger, respectively, contain limitations similar to those discussed above with respect to new claims 21 and 25.

Thus, for at least the reasons discussed above, claims 12 and 15 are allowable as well.

Claims 2-11 and 22 are allowable at least due to their dependence from new claim 21, claims 13-14 are allowable at least due to their dependence from amended claim 12, and claims 16-20 and 23-24 are allowable at least due to their dependence from amended claim 15.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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